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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,802	01/13/2004	Cynthia C. Bamdad	M1015.70070US01	1525
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JHK LAW P.O. BOX 1078 LA CANADA, CA 91012-1078			EXAMINER FORMAN, BETTY J	
			ART UNIT	PAPER NUMBER
			1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/31/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/756,802

Applicant(s)

BAMDAD ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 119-131 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 119-131 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## **FINAL ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 20 November 2006 in which claim 1 was amended and claims 119-131 were added. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 19 May 2006 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 1, 119-131 are under prosecution.

### ***Information Disclosure Statement***

2. The IDS submitted August 2006 have been reviewed. The references listed on the 1449 have been reviewed as indicated on the initialed copy of the 1449s provided with this action. The references lined-through have not been considered because the references are not English Language documents.

### ***Claim Rejections - 35 USC § 112***

#### **35 U.S.C. 112: First Paragraph**

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 131 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described

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in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New Claim 131 recites “deactivating an non-hybridized oligonucleotide”. However, the specification provides no support for the newly claimed “deactivating”. Applicant generally points to the originally filed claims to support the new claims. However, no such support has been found in the originally filed claims or specification as a whole.

### **35 U.S.C. 112: Second Paragraph**

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 and 119-131 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1 and 119-131 are indefinite in Claim 1 for the recitation “the oligonucleotide identifier associated with the surface” because the “associated with” lacks proper antecedent basis in the “immobilized” identifier of line 2. It is suggested the claim be amended to provide proper antecedent basis e.g. replace “associated with” with “immobilized on”.

b. Claims 122 is indefinite for the recitation “the chemical or biological species is fastened to the surface” because “fastened” lacks proper antecedent basis in the immobilized species of Claim 1. It is suggested the claim be amended to provide proper antecedent basis e.g. replace “fastened” with “immobilized”.

c. Claim 122 is further indefinite for the recitation “metal binding tag/metal/chelate linkage” because it is unclear what is encompassed by the “/”. It is unclear whether the “/” represents a comma, the term “or”, or the phrase “and/or”. Furthermore it is unclear whether the recitation is a Markush Group such that the species is fastened by any one of the terms listed. The recitation is further indefinite because it is unclear whether “linkage” modifies only

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“chelate” or whether “linkage” is intended to modify each of the metal binding tag, metal and chelate. It is suggested the claim be amended to clarify.

d. Claims 123 and 124 are each indefinite for the recitation “the oligonucleotide identifier is fastened to the surface” because “fastened” lacks proper antecedent basis in the immobilized species of Claim 1. It is suggested the claim be amended to provide proper antecedent basis e.g. replace “fastened” with “immobilized”.

e. Claim 125 is indefinite because it is unclear whether the claim is defining the identifying step of Claim 1 or whether the claim is requiring an additional identifying step. It is suggested the claim be amended to clarify.

f. Claim 126 is indefinite for the recitation “the allowing step comprising allowing a first species, fasted to a surface, to biologically bind to a second species fastened to a second surface”. The recitation is indefinite because the allowing step of Claim 1 does not include a first and second species, does not include any species “fastened” to a surface, does not include a second surface and does not include biological binding. Therefore the recitation lacks proper antecedent basis in the “**a** chemical or biological species”, “immobilization” and “interaction” of Claim 1. The recitation is further indefinite because it is unclear whether it is intended to further define the interaction of line 3 of Claim 1 by adding a second species and surface involved with the interaction.

g. Claim 126 is further indefinite in line 4 because it is unclear whether the “determining” is defining the determining step of Claim 1 or is defining a second/additional determining step.

h. Claim 126 is also indefinite in lines 6-8 because it is unclear whether the “identify” is defining the identifying of Claim 1 or is defining a second/additional identifying step.

i. Claim 126 is further indefinite for the recitation “an oligonucleotide identifier which was fastened to the surface of the second article during the allowing step” because neither the

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allowing step of Claim 1 or 126 “fastens” the identifier and neither Claim 1 or 126 recites a “second article”. It is suggested Claim 126 be amended to clarify.

j. Claim 127 is indefinite for the recitation “the first and second articles” because the “articles” lack proper antecedent basis in the surface of Claim 126.

k. Claim 128 is indefinite because it is unclear whether the claim is defining the identifying step of Claim 1 or whether the claim is requiring an additional identifying step. It is suggested the claim be amended to clarify.

l. Claim 129 is indefinite because it is unclear whether the claim is defining the allowing and determining steps of Claim 1 or whether the claim is requiring an additional allowing and determining steps. It is suggested the claim be amended to clarify.

m. Claim 129 is further indefinite for the recitation “immobilized relative to a surface” because “relative to a surface” lacks proper antecedent basis in the “immobilized on a surface of Claim 1. The recitation is further indefinite because it is unclear what is encompassed by “relative” i.e. is the species immobilized?

n. Claim 129 is also indefinite in lines 5-6 for the recitation “identifying an interaction hybridization identifier” because it is unclear whether an interaction or hybridization is being described.

o. Claim 130 is indefinite because it is unclear whether the claim depends on any elements of Claim 1. It is unclear whether the allowing and identifying steps modify the allowing and identifying of Claim 1 or whether the steps require additional steps of allowing and identifying. Claim 130 appears to be an independent claim. As such, it improperly depends from Claim 1.

p. Claim 130 is also indefinite for the recitation “an interaction hybridization identifier” because it is unclear whether an interaction or hybridization is being described.

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q. Claim 131 is indefinite for the recitation "deactivating any non-hybridized oligonucleotide" because the oligonucleotides of Claims 1 and 130 are not "activated". Therefore it is unclear what is encompassed by the claimed "deactivating".

### ***Claim interpretation***

7. As discussed above, the claims have numerous indefinite, conflicting and confusing recitations. For example, some dependent claims appear to be independent because they do not define "further" elements or define further limitations of the independent claims. Furthermore, numerous dependent claims use terminology that differs from the claims from which they depend. For these reasons, the scope of the dependent claims is often unclear. For purposes of examination, the claims are interpreted as described below.

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 119-131 are rejected under 35 U.S.C. 102(b) as being anticipated by Mirkin et al (WO 98/04740, published 5 February 1998).

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Regarding Claim 1, Mirkin et al disclose a method comprising allowing a biological species (Analyte DNA) and an oligonucleotide identifier (i.e. DNA modified colloid) immobilized on a common surface (transparent substrate and colloid) to participate in an interaction and determining participated by identifying the identifier associated with the surface (Example 6, pages 72-74 and Fig. 13).

Mirkin et al also disclose other embodiments encompassed by the claimed method comprising allowing a biological species (linking oligonucleotide) and an oligonucleotide identifier (oligo-modified colloid) immobilized on a common surface (aggregate comprising colloid) to participate in an interaction and determining participated by identifying the identifier associated with the surface (Fig. 4-5).

Regarding Claim 119, Mirkin et al disclose the method wherein the surface comprises gold (i.e. the colloids are gold, page 19, lines 24-27). The instant claim defines the common surface as gold. Mirkin teaches a complex comprising substrate immobilized linking oligonucleotide "A", analyte DNA A'B' and colloid immobilized oligonucleotide B (Fig. 13). Upon hybridization as illustrated in 13A/B, all the components of the complex are co-immobilized i.e. the linker is immobilized to the analyte which is immobilized to the colloid. Mirkin et al also teach embodiments comprising two colloid surfaces (e.g. Fig. 4-5) wherein upon hybridization all of the analyte and identifier are co-immobilized to colloids. Therefore the common immobilization surface comprises a gold colloid as claimed.

Regarding Claim 120, Mirkin et al disclose the method wherein the surface is a gold colloid (page 19, lines 24-27 and Fig. 13).

Regarding Claim 122, Mirkin et al disclose the embodiment wherein the biological species is fastened to the surface via metal binding target (e.g. alkanethiol to gold, page 21, lines 8-35).

Regarding Claim 126, Mirkin et al disclose an embodiment comprising a first species immobilized to a first colloid (e.g. linking oligonucleotide immobilized via hybridization to the 3'



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colloid) allowing the first species to bind to a second species (e.g. 5' colloid) determining immobilization of first surface relative to the second and identifying an oligonucleotide identifier (e.g. 3' colloid) which was immobilized to the second surface during hybridization (Fig. 4).

Regarding Claim 127, Mirkin et al disclose the surfaces are colloids (Fig. 4).

Regarding Claim 128, Mirkin et al disclose the method of Claim 1 wherein the identifying comprises identifying an oligonucleotide (linking oligonucleotide) having a first portion complementary to the identifier (3' oligo-colloid) and a second portion complementary to a second identifier (5' oligo-colloid, Fig. 4-5).

#### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 121 and 124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mirkin et al (WO 98/04740, published 5 February 1998) in view of Sigal et al (U.S. Patent No. 6,319,670, filed 23 December 1997).

Regarding Claims 121 and 124, Mirkin et al disclose a method comprising allowing a biological species (Analyte DNA) and an oligonucleotide identifier (i.e. DNA modified colloid) immobilized on a common surface (transparent substrate and colloid) to participate in an interaction and determining participated by identifying the identifier associated with the surface (Example 6, pages 72-74 and Fig. 13). Mirkin et al also teach the immobilized to the

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gold particles uses a thiol-linkage (e.g. alkanethiol to gold, page 21, lines 8-35) but is silent regarding a self-assembled monolayer. However, biological molecules immobilized to gold particles via thiol linkage and self-assembled monolayers were well known in the art at the time the claimed invention was made as taught by Sigal et al who teach that the monolayer promotes generation of ELC labels (Column 8, lines 8-31). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the monolayer of Sigal et al to the gold particles of Mirkin et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success for the benefit of promoting detection of ECL labels as taught by Sigal et al (Column 8, lines 8-31).

12. Claims 123, 125, 129-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mirkin et al (WO 98/04740, published 5 February 1998) in view of Hunkapiller et al (U.S. Patent No. 5,942,609, issued 24 August 1999).

Regarding Claims 123, 125, 129-131, Mirkin et al disclose a method comprising allowing a biological species (Analyte DNA) and an oligonucleotide identifier (i.e. DNA modified colloid) immobilized on a common surface (transparent substrate and colloid) to participate in an interaction and determining participated by identifying the identifier associated with the surface (Example 6, pages 72-74 and Fig. 13). Mirkin et al also disclose other embodiments encompassed by the claimed method comprising allowing a biological species (linking oligonucleotide) and an oligonucleotide identifier (oligo-modified colloid) immobilized on a common surface (aggregate comprising colloid) to participate in an interaction and determining participated by identifying the identifier associated with the surface (Fig. 4-5). Mirkin et al also teach that prior to identification non-hybridized oligonucleotides are removed, thereby deactivating any activity they may provide to the reaction (paragraph spanning pages 30-31).

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Mirkin et al further teach integration of an oligonucleotide between the first and second identifiers (Fig. 3) but they do not teach separating the identifier prior to identification, fluorescent sequencing and/or adding a hybridization identifier complementary to the first and second identifiers.

However, Hunkapiller et al teach a similar method of method of contacting a nucleic acid with adjacent oligonucleotides (identifiers), ligating the adjacent oligonucleotides , removing the ligated oligonucleotides prior to detection wherein the detection uses a "bridging nucleotide" complementary to both identifiers (Column 10, lines 59-62). Hunkapiller et al further teach fluorescent sequencing to identify the ligation product via Sanger didoxy DNA sequencing and/or real time PCR using a fluorescent probe specific for the ligation product (Column 15, lines 5-60). Hunkapiller et al further teach the method of fluorescent sequencing (real-time PCR) is the preferred when quantitative measurement is desired (Column 15, lines 56-60). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the separation of the identifier (ligated oligos) followed by real-time PCR of Hunkapiller et al to the method of Mirkin. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the preferred teaching of Hunkapiller et al and for the expected benefit of obtaining quantitative measurement as desired in the art Hunkapiller et al (Column 15, lines 56-60).

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Conclusion***

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

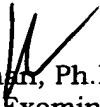
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
BJ Forman, Ph.D.  
Primary Examiner  
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January 25, 2007